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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,018	11/21/2005	Khaled Awad Saleh Nashwan	9007-1012	1412

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EXAMINER	
FARAH, AHMED M	

ART UNIT	PAPER NUMBER
3769	

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04/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,018	NASHWAN, KHALED AWAD SALEH	
	Examiner	Art Unit	
	Ahmed M. Farah	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/24/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *55-59 and 63* is/are allowed.

6)☒ Claim(s) *38-54 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The amendment filed on December 1, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "pulse strength meter" for measuring strength of patient pulses.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description as originally filed failed to teach '*a pulse strength meter*' as recited in the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 40-47, 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recite the terms "a second surface carrying several **exciting means**" in lines 5-6. It is not clear r whether the applicants want to invoke the 35 U.S.C. 112, sixth paragraph.

When it is not clear whether a claim limitation should be treated under 35 U.S.C. 112, sixth paragraph, determining the patentability of that claim is difficult because the scope of the claim and the relevance of the prior art cannot be readily determined. Applicants have an opportunity and obligation to define their inventions precisely during proceedings before the PTO. They are required to specify their inventions, consistent with the guidelines described in MPEP 2181, when a claim limitation invokes 35 U.S.C. 112, sixth paragraph.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for" or "step for";

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the applicants wish to have the claim limitations under 112, sixth paragraph interpretation, they must: show why the claim language properly invokes 35 U.S.C. 112, sixth paragraph; identify the function; and identify the corresponding structure. They must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112 , sixth paragraph. See Watts v. XL Systems, Inc., 232 F.3d 877, 56 USPQ24 1836 (Fed. Cir. 2000).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 38, 39, 51, 54, 54 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Brisken et al. US Patent No. 6,575,956.

Brisken et al. disclose an ultrasound delivery system including a piezoelectric element of an ultrasound transducer that is generally planar and may either be rectangular, circular, or annular in shape. The transducer may comprise a

plurality of annular-shaped piezoelectric elements disposed concentrically, one within another (Col. 4, lines 40-45). The transducers may be fabricated from single crystal piezoelectrics, (Col. 11, lines 30-32) and are coupled to the target area by a coupling material (Fig. 11, # 113). The user operates the system through a user interface (Fig. 14, # 141) to a computer or controller subsystem. Through a digital I/O device (Fig. 14, # 143), the computer controls a signal generator to generate the RF driving signal, a modulator to format the number of cycles per burst and to set the burst rate, a variable gain power amplifier, an impedance matching circuit, and finally the transducer (Col. 12, lines 50-57). The ultrasound is produced at frequencies from 20 kHz to 5 MHz (Claim 20). The intensity is disclosed as from 0.01 to 100 W/cm^2 (table 3).

5. Claims 38, 39, 48, 49, 52 and 53 rejected under 35 U.S.C. 102(e) as being anticipated by Prausnitz et al. US Patent No. 7,273,458 (hereinafter *Prausnitz*).

Prausnitz discloses a medical apparatus for applying acoustic energy in the frequency range of between 1 Hz and 100 MHz to body tissue being treated, the apparatus comprising ultrasonic transducer and control means for monitoring and controlling the output energy of the transducer.

With respect to claim 48, Prausnitz further discloses a means for monitoring temperature change in the tissue induced by the applied acoustic waves.

With respect to claim 49, Prausnitz further teaches the use of pulse strength measuring device for measuring strength of the acoustic energy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prausnitz in view of Thompson et al. US Patent No. 6,790,187.

Prausnitz, described above, does not teach a gel as a coupling medium as claimed. However, the use of liquid medium such as water, gel, etc. for coupling acoustic energy to body tissue is known in the art. For example, doctors/nurses generally apply gel to the belly of a pregnant woman during sonogram procedure for monitoring pregnancy. Thompson discloses an alternative apparatus and methods of use for applying sound waves to a body region wherein liquid gel is used as coupling medium. Therefore, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify Prausnitz in view of Thompson to use gel as medium for coupling the ultrasonic transducer to a body region.

Allowable Subject Matter

7. Claims 55-59 and 63 are allowed.

Response to Arguments

8. Applicant's arguments filed on December 1, 2008 have been fully considered but they are not persuasive. The applicant argues that the treatment energy of the instant claims is a combination of infra and audible sound waves in the range of between 1Hz to 100 KHz. The applicant further argues the frequency of the sound waves applied to tissue "is being continuously changed over time in one treatment cycle."

In response to the first argument, independent claim 38 recites apparatus **comprising** a treatment head for emitting sound waves in the frequency range of between 1 Hz to 100 KHz. The transitional phrase **comprising** is an open ended term and does not exclude additional, unrecited elements and/or step. Moreover, the frequency range of Brisken et al falls within the range of the recited frequencies. With respect to the second argument, the recited claim language is directed to method steps of carrying out the treatment. With respect to the apparatus claims, this argument is not given a patentable weight as the cited claim language fails to incorporate any functional and/or structural limitation to further limit the claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon, Tue, Thur and Fri between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johnson Henry can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ahmed M Farah/
Primary Examiner, Art Unit 3769

April 26, 2009.